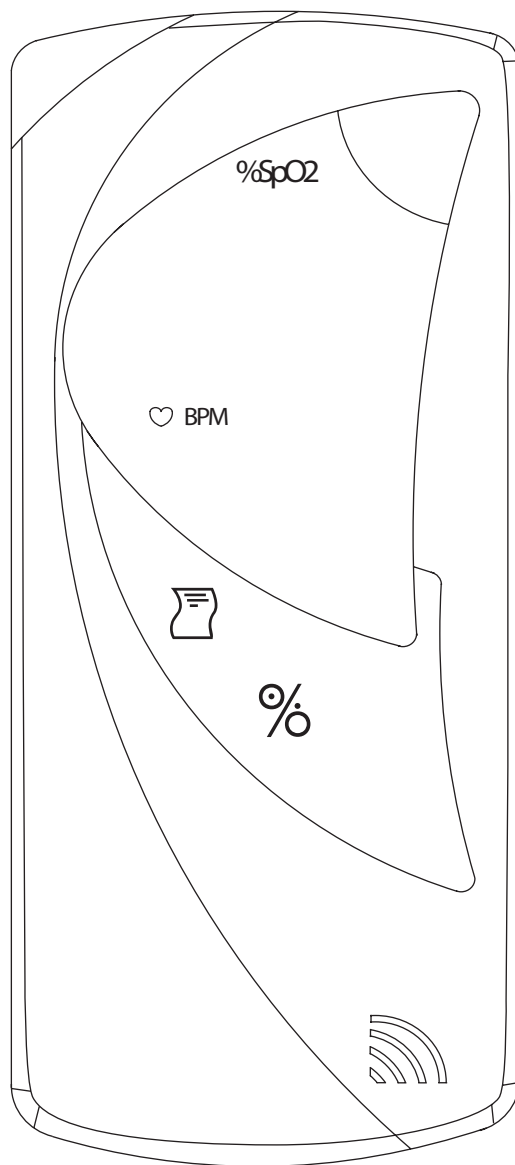


# Pulse Oximeter for Sleep Screening

## Operation Manual



**en** English

Catalog Number 1884SS

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## Warranty & Service Information

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### Proprietary Notice

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain, and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

### Warranty

#### Limited Warranty

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling for one year from the date of shipment to the original purchaser (USA only).

#### Disclaimer of Warranties

**THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

Seller disclaims responsibility for the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

#### Conditions of Warranty

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

#### Limitation of Remedies

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. **THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based in contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues and profits.**

## Warranty Procedure

To obtain warranty service in the USA, you must request a Customer Service Report (CSR) number from Technical Service. Reference the CSR number when returning your Product, freight and insurance prepaid, to:

Smiths Medical PM, Inc.  
N7W22025 Johnson Drive  
Waukesha, Wisconsin 53186-1856

Phone: (262) 542-3100  
Fax: (262) 542-0718  
Toll Free: (800) 558-2345 (USA only)  
email: [info.pm@smiths-medical.com](mailto:info.pm@smiths-medical.com)

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

## CE Notice

Marking by the symbol  indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd.  
Colonial Way, Watford, Herts  
WD24 4LG, UK

Telephone: (44) 1923 246434  
Fax: (44) 1923 240273

# Chapter 1: Introduction

## About this Manual

The Operation Manual provides installation, operation, and maintenance instructions for health-care professionals and other users, trained in monitoring respiratory and cardiovascular activity.

**These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the oximeter. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.**

## Definition of Symbols

| SYMBOL                                                                              | DEFINITION                                                                                     |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
|    | Type BF Equipment                                                                              |
|    | Attention, see instructions for use                                                            |
|    | Refer servicing to qualified service personnel                                                 |
|    | Serial Number                                                                                  |
|    | Catalog Number                                                                                 |
|    | Printer On/Off                                                                                 |
|   | Date of Manufacture                                                                            |
|  | On/Off                                                                                         |
|  | Non AP device                                                                                  |
|  | Do not reuse. One use on one patient.                                                          |
|  | Batch Code                                                                                     |
|  | Use By                                                                                         |
| <b>IPX1</b>                                                                         | Drip Proof                                                                                     |
|  | Collect Separately                                                                             |
| <b>Rx ONLY</b>                                                                      | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. |
| KEYWORD                                                                             | DEFINITION                                                                                     |
| <b>WARNING</b>                                                                      | Tells you something that could hurt the patient or hurt the operator.                          |
| <b>CAUTION</b>                                                                      | Tells you something that could damage the monitor.                                             |
| <b>NOTE</b>                                                                         | Tells you other important information.                                                         |

## Warnings

**WARNING!** Do not use this device in the presence of flammable anesthetics.

**WARNING!** Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

**WARNING!** Operation of this device may be adversely affected in the presence of conducted transients or strong EM or RF sources, such as electrosurgery and electrocautery equipment, x-rays, and high intensity infrared radiation.

**WARNING!** Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

**WARNING!** This device is intended for use by persons trained in professional health care or those who have access to the oversight of a professional health care provider. The operator must be thoroughly familiar with the information in this manual and/or the “Home User’s Guide” before using the device.

**WARNING!** This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

**WARNING!** If the accuracy of any measurement is in question, verify the patient’s vital sign(s) by an alternative method and then check the monitor for proper functioning.

**WARNING!** Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure proper operation.

**WARNING!** Prolonged use or the patient’s condition may require changing the sensor site periodically. Patients setting up the device at home should be instructed of the signs/symptoms of sensor misuse (e.g., pressure sores from prolonged application) and should be advised to move the sensor to another finger if necessary.

**WARNING!** When attaching sensors with Microfoam<sup>®</sup> tape, do not stretch the tape or attach the tape too tightly. Any device (tape, VELCRO<sup>®</sup>) applied too tightly may cause inaccurate readings and blisters on the patient’s skin (lack of skin respiration, not heat, causes the blisters).

**WARNING!** Incorrectly applied sensors may give inaccurate readings. Refer to the sensor insert for proper application instructions.

**WARNING!** Use only SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device.

**WARNING!** SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

**WARNING!** Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO<sub>2</sub> reading.

**WARNING!** Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO<sub>2</sub> readings.

**WARNING!** Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

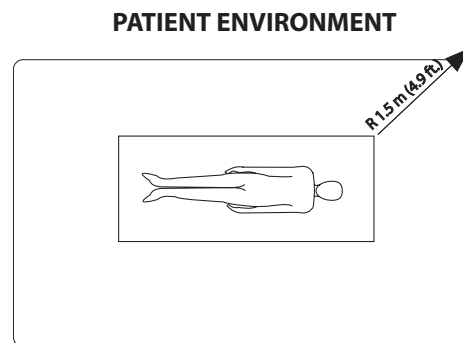
**WARNING!** Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.

**WARNING!** Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO<sub>2</sub> measurement.

**WARNING!** Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

**WARNING!** When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

**WARNING!** IEC 950 approved equipment must be placed outside the "patient environment". The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.



**WARNING!** Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

**WARNING!** Remove device batteries prior to long term storage.

**WARNING!** Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

## Cautions

- CAUTION!** Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid. Evidence that liquid has been allowed to enter the monitor voids the warranty.
- CAUTION!** Connect only the PC cable specifically intended for use with this device (see *Optional Supplies and Accessories*).
- CAUTION!** When printing, or advancing the paper, place the oximeter on its' side to prevent paper jams.
- CAUTION!** Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

## Notes

- NOTE!** Batteries are designed to be replaceable by individuals trained in this procedure. Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.
- NOTE!** SpO<sub>2</sub> averaging is the number of pulse beats over which the SpO<sub>2</sub> value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.
- NOTE!** All user and patient accessible materials are non-toxic.

---

## Chapter 2: Intended Use and Monitor Features

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### Intended Use

This device is a handheld pulse oximeter that measures SpO<sub>2</sub>, pulse rate, and pulse strength. It may be used as a spot check device in the hospital or clinical environments. Additionally, it may be used to collect long term data in overnight sleep screening studies in the sleep lab or home. The oximeter will provide reliable measurements on patients ranging from neonate to adults for spot checking applications and from pediatric to adult for sleep screening applications when using the appropriate catalog accessories. The oximeter will operate accurately over an ambient temperature range of 0 to 55°C (32 to 131°F).

This device is not intended for continuous patient monitoring, but can be used for spot checking and/or long-term data collection applications. There are no audible or visible patient alarms.

### Monitor Features

- Provides fast, reliable SpO<sub>2</sub>, pulse rate, and pulse strength measurements on any patient, from neonates to adults for spot-checking applications and on pediatric to adults for sleep screening applications.
- Ideally suited for use in overnight sleep screening applications allowing printing of summated data results.
- Three modes of operation: Verification Mode for spot checking, Data Collection Mode for long term data collection in sleep screening environments and Trend Printing Mode for outputting summarized trend data to the built-in printer or to a PC.
- Device automatically enters Data Collection Mode after 10 minutes of continuous use.
- Minimal LED display during Data Collection Mode lengthens battery life (i.e. – display is reduced to a single flashing bar).
- Portable and lightweight. Weighs only 13 ounces (369 grams), with batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses four (4) standard “AA” (type IEC LR6) alkaline cells.
- Battery life (Alkaline Cells):
  - 2 sleep screening cycles (1 cycle = 10 minutes with display on, 8 hours with display off, 5 minutes printing)
  - Intermittent monitoring: 1 min on, 2 min off (= 1 cycle) 80 hours or 1600 cycles.
- Bright, easy-to-read LED displays indicate SpO<sub>2</sub> and pulse rate measurements.
- An eight-segment LED bar graph indicates pulse strength in the Verification Mode.
- Low Battery Indicator flashes when about 30 minutes of battery use remains.
- Capable of 12 hours of data storage.

## Theory of Operation

The pulse oximeter determines %SpO<sub>2</sub> and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the *SpO<sub>2</sub> Specifications* section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

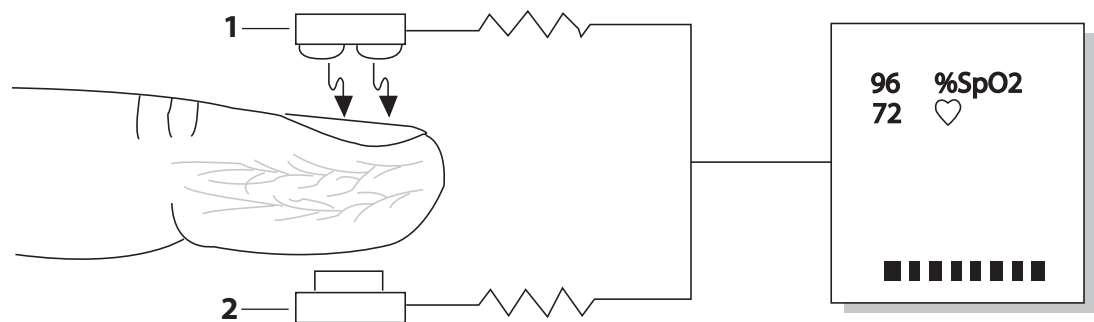


Figure 2.1: Theory of Operation

### 1) Low intensity Red and Infrared LED light sources

### 2) Detector

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO<sub>2</sub>) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

**WARNING!** Since measurement of SpO<sub>2</sub> depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO<sub>2</sub> and pulse rate readings.

**WARNING!** Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

## Chapter 3: Controls and Features

### Monitor Front Panel

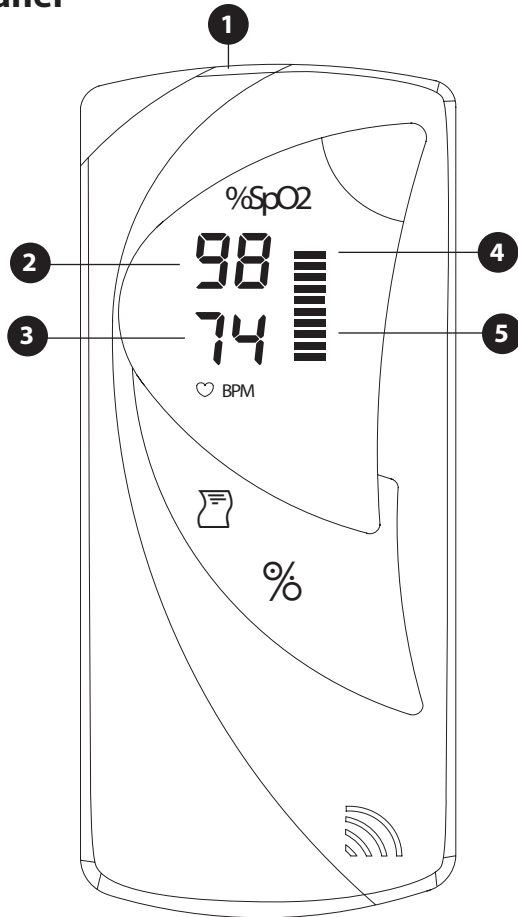


Figure 3.1: Monitor Front Panel

#### 1 Sensor/Serial Connector

The sensor connects here, or an oximetry cable can be connected between the monitor and the sensor. The serial printer or PC communication cable is also connected here.

#### 2 SpO<sub>2</sub> Numeric Display

A number shows the patient's SpO<sub>2</sub> value in percent. Dashes (--) mean the monitor is not able to calculate the SpO<sub>2</sub> value in Verification Mode. SpO<sub>2</sub> display in Data Collection Mode will be one flashing bar to conserve battery life.

#### 3 Pulse Rate Numeric Display

A number shows the patient's pulse rate value in beats per minute. Dashes (---) mean the monitor is not able to calculate the pulse rate value in Verification Mode. In Data Collection Mode, the Heart Rate display will be blank to conserve battery life.

#### 4 Low Battery Indicator

Low Battery is indicated by the top bar graph LED quickly flashing about once per second.

#### 5 Pulse Strength Bar Graph

In Verification Mode, the pulse strength bar graph "pulses" with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

## Monitor Operating Keys

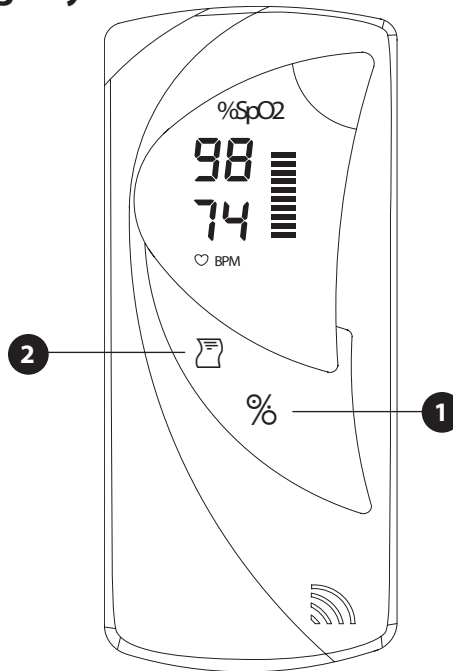


Figure 3.2: Monitor Operating Keys

### 1 % ON OFF Key

Pressing this key turns the monitor ON and OFF.

### 2 PRINT Key

- **Verification Mode:** In this mode, momentarily pressing the  key will not activate the printer as the printer function is suppressed in this mode. Pressing and holding the  key in the Verification Mode will advance the paper. Reloading the paper is allowed in this mode. Pressing and holding the  key at power up will erase trends, even if the trend memory is clear.
- **Data Collection Mode:** In this mode, momentarily pressing the  key will not activate the printer as the printer function is suppressed in this mode. However, in the Data Collection Mode, pressing and holding this key will advance the paper in the printer. Reloading the paper is allowed in this mode.
- **Trend Printing Mode:** Momentarily pressing the  key will activate a printout (statistical sleep screening information). Pressing the  key during the printout will terminate the printout. Pressing and holding the  key will advance the paper. Holding the  key for 6 to 8 seconds at power up will clear the trend and switch the unit into Verification Mode. Reloading the paper is allowed in this mode.

**NOTE! All data will be irretrievably lost when the trend data is cleared.**

See Chapter 4 for more details on the three modes.

---

## Chapter 4: Operating Instructions

---

**WARNING!** This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

### Unpacking the Monitor

1. Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

### Installing the Batteries

The oximeter uses 4 standard "AA" alkaline cells, IEC Type LR6.

To install/replace the batteries:

1. Depress the battery door tab and lift up.
2. Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive tab. Press the battery down into place.
3. Place battery door tabs into the slots of the monitor back panel, depress the door tab and press the door into place.

**NOTE!** If you install disposable batteries, be sure to dispose of them in compliance with your institution's guidelines and local ordinances.

**NOTE!** The unit will hold data for about one and a half minutes with no battery power. This allows for battery replacement without loss of stored data.

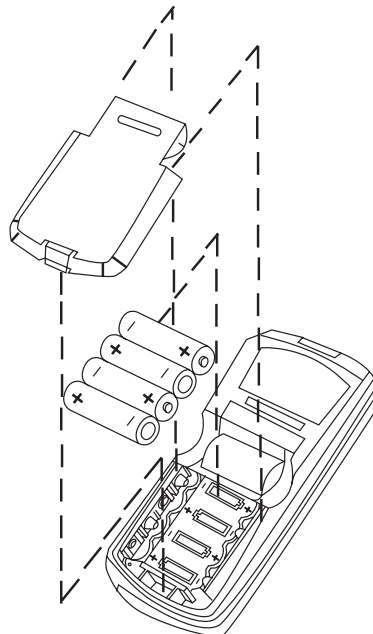


Figure 4.1: Installing the Batteries

## Attaching the Sensor to the Patient

**WARNING!** Prolonged use or the patient's condition may require changing the sensor site periodically. Patients setting up the device at home should be instructed of the signs/symptoms of sensor misuse (e.g., pressure sores from prolonged application) and should be advised to move the sensor to another finger if necessary.

**WARNING!** When attaching sensors with Microfoam<sup>®</sup> tape, do not stretch the tape or attach the tape too tightly. A sensor applied too tightly by any method (tape, VELCRO<sup>®</sup>) may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

Attaching the patient to the monitor requires these steps:

1. Choose the sensor.
2. Check the sensor and oximetry cable.
3. Clean or disinfect the sensor if using the reusable type. (Disposable sensors are for single-patient use and do not require cleaning or disinfecting.)
4. Attach the sensor to the patient.

## Choosing the Sensor

Choose the appropriate sensor from the following chart.

| PATIENT                            | SITE          | DESCRIPTION                                                                                                                       |
|------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Adult<br>> 45 kg                   | Finger        | 3044: Sensor, Oximetry, Adult, Finger (reusable)<br>3444: Sensor, Oximetry, Comfort Clip <sup>®</sup> Finger (reusable)           |
|                                    | Finger or Toe | 3043: Sensor, Oximetry, Universal 'Y' (reusable)                                                                                  |
|                                    | Ear           | 1300: Sensor, Oximetry, Disposable, Adult Finger (X)                                                                              |
|                                    |               | 3078: Sensor, Ear (reusable)                                                                                                      |
| Pediatric<br>15-45 kg              | Finger        | 3044: Sensor, Oximetry, Adult, Finger (reusable) (> 20 kg)<br>3444: Sensor, Oximetry, Comfort Clip <sup>®</sup> Finger (reusable) |
|                                    | Finger or Toe | 3178: Sensor, Pediatric Finger, reusable (5-45 kg)<br>3043: Sensor, Oximetry, Universal 'Y' (reusable)                            |
|                                    | Ear           | 1301: Sensor, Oximetry, Disposable, Pediatric Finger (X)                                                                          |
|                                    |               | 3078: Sensor, Ear (reusable)                                                                                                      |
| Infant<br>3-15 kg                  | Hand or Foot  | 3043: Sensor, Oximetry, Universal 'Y' (reusable)                                                                                  |
|                                    | Toe           | 3025: Sensor, Oximetry, Wrap, Infant (reusable)                                                                                   |
|                                    | Finger or Toe | 1303: Sensor, Oximetry, Disposable, Infant (X)                                                                                    |
| Small Infant<br>>30 days<br>< 3 kg | Hand or Foot  | 1302: Sensor, Oximetry, Disposable, Neonate (X)                                                                                   |
|                                    | Foot          | 3026: Sensor, Oximetry, Wrap, Neonate (reusable)                                                                                  |

## Care and Handling of the Sensor

**WARNING! Misuse or improper handling of the sensor and cable could result in damage to the sensor. This may cause inaccurate readings.**

Hold the connector rather than the cable when connecting or disconnecting the sensor to the device as shown in Figure 4.2.

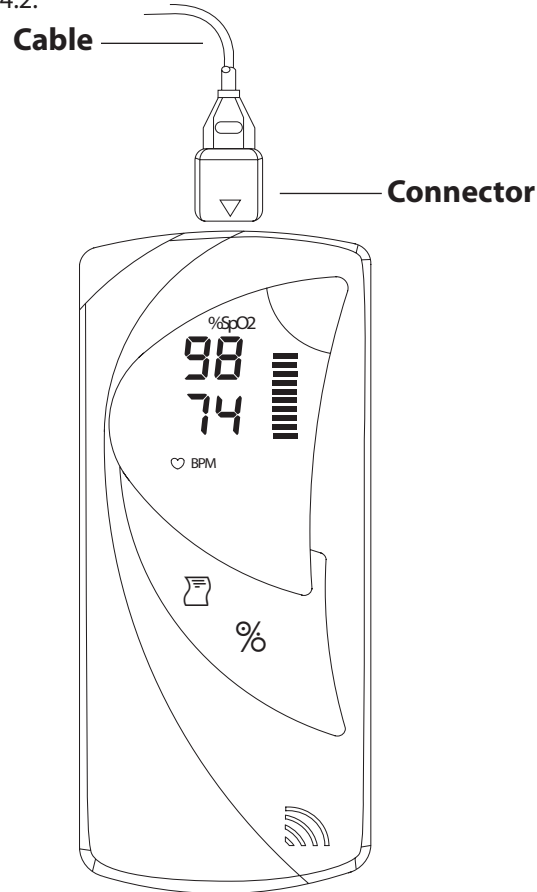


Figure 4.2: Disconnecting or connecting the sensor.

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or using the sensor.

When placing the sensor on the patient, allow the cable to lay across the palm of the hand and parallel to the arm of the patient as shown in Figure 4.3.

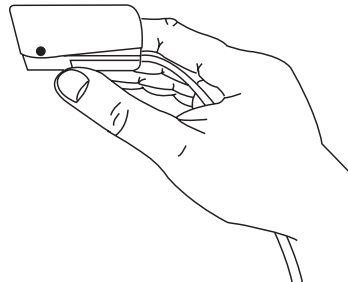


Figure 4.3: Positioning the cable of the finger sensor.

Upon completion of patient monitoring, detach the sensor as shown in Figure 4.2 and loosely coil the finger sensor cable.

## Checking the Sensor and Oximetry Cable

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable is working properly.

**WARNING! Using a damaged sensor may cause inaccurate readings. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help.**

**WARNING! Using a damaged oximetry cable may cause inaccurate readings. Inspect the oximetry cable. If the oximetry cable appears damaged, do not use it. Contact your authorized repair center for help.**

1. Carefully inspect the sensor to make sure it does not appear damaged.
2. If using the oximetry cable:
  - a. Carefully inspect the oximetry cable to make sure it does not appear damaged.
  - b. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable. Carefully align and push the connectors together firmly and close the latch to secure the connectors.
  - c. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor. Carefully align and push the connector firmly into the monitor.
3. If not using the oximetry cable, connect the sensor to the monitor. Push the connector firmly into the monitor.
4. If the monitor is not already on, press the  $\%$  key to turn on the monitor.

**WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.**

5. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter by making sure the red light in the sensor is illuminated.

**NOTE! Obstructions or dirt on the sensor's red light or detector may cause the integrity checks to fail. Make sure there are no obstructions and the sensor is clean.**

6. You are now ready to attach the sensor to the patient.

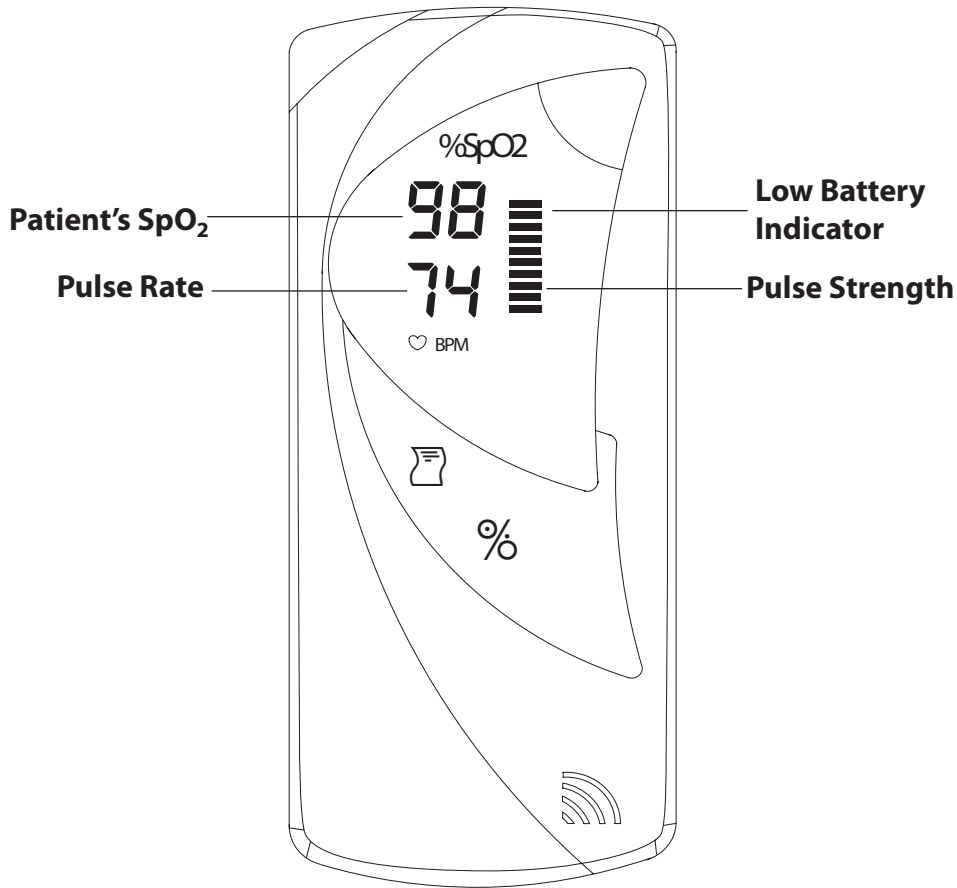
## Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.

**WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.**

**CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.**

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

Figure 4.4: SpO<sub>2</sub>, pulse rate, and pulse strength bar graph.

## Turning On the Monitor

To turn on the monitor, press the % key.

**WARNING!** Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

## Low Battery Indicator

- The Low Battery Indicator is the top LED segment of the pulse strength bargraph.
- The Low Battery Indicator will flash rapidly when the batteries need to be replaced.
- The Low Battery Indicator will flash rapidly if the monitor is trying to print and there is not enough battery life for printing.

**WARNING!** When the LOW BATTERY INDICATOR flashes, you must immediately replace the monitor's batteries. Otherwise, the monitor turns itself off about 30 minutes after the highest bargraph LED begins to flash in any mode.

## Turning Off the Monitor

Turn off the monitor when you are not monitoring a patient.

To turn off the monitor, press the  $\%O_2$  key. To turn off the monitor in the Data Collection Mode, the  $\%O_2$  key must be pressed and held for 6 seconds.

**NOTE!** Once the monitor is powered off in the Data Collection Mode, it cannot resume collection of trend data without clearing all previously obtained data.

## Checking the Monitor's Performance

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximetry/Patient Simulator (Catalog No. 1606) is available as an accessory. The simulator attaches to the oximeter via the 3311 oximetry cable. It provides a known  $SpO_2$  and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

**NOTE!** The 1606 Oximetry/Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known  $SpO_2$  and pulse rate to the monitor that allows you to check the monitor's performance.

**NOTE!** The 1606 Oximetry/Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.

**NOTE!**  Follow the instructions included with the 1606 Oximetry/Patient Simulator.

## Operating Modes

The monitor has three operating modes: Verification Mode, Data Collection Mode, and Trend Printing Mode.

- Verification Mode is intended for use in spot checking and for verification of correct sensor placement.
- Data Collection Mode is intended for use in long-term data collection in sleep screening environments.
- Trend Printing Mode is intended for use in the output of the trend data summation to the printer or a full computer data download.

## Verification Mode

Verification Mode is intended for use in spot checking and for verifying that the user has correct placement of the finger sensor.

1. The monitor will enter the Verification Mode as soon as trend memory is cleared.
2. In this mode the patient will be able to position the sensor on his/her finger (or appropriate site) and obtain SpO<sub>2</sub> and heart rate data on the display.
3. This mode will last for 10 minutes of continuous valid data collection.
4. If the monitor is powered down during this mode, it will be powered up in this mode and the verification timer will be reset.
5. Once the verification timer reads 10 minutes, the monitor exits the Verification Mode and enters the Data Collection Mode.
6. The user functions in Verification Mode are:
  - The display will show % SpO<sub>2</sub> and heart rate values (if available, otherwise “dashes” [ - - ] for invalid data are displayed).
  - The % key will turn the unit OFF without changing modes.
  - Pressing the  key momentarily will not activate the printer. The printer function is suppressed in this mode.
  - Pressing and holding the  key will advance the paper (see pg. 7-5) Reloading the paper is allowed in this mode.
  - Pressing and holding the  key at power up will erase trends, even if the trend memory is already clear.
  - The serial link to the PC computer will be suppressed in this mode.

## Data Collection Mode

Data Collection Mode is intended for use in long-term collection of data in sleep screening environments.

1. The Data Collection Mode will be entered when the verification timer reaches 10 minutes.
2. Once the trend data collection process has been started, trend memory will be filled continuously until the end-of-memory is detected (approx. 12 hours) or the monitor is powered down.
3. Invalid data (such as sensor off) is stored in trend memory, but is not used in the statistical calculations.
4. The user functions in Data Collection Mode are:
  - The SpO<sub>2</sub> display will show one flashing bar and heart rate display will be blank (see Fig. 4.5).
  - Pressing and holding the % key for six (6) seconds will turn off the unit. While pressing the % key, the flashing bar will flash at a higher frequency indicating that the unit is about to be powered down.

**NOTE! If the % key is released before the six seconds elapses, the bar will return to its normal flashing pattern.**

- After the power down, the unit will power up in the Trend Printing Mode.

**NOTE! Once the monitor is powered off in the Data Collection Mode, it cannot resume collection of trend data without clearing all previously obtained data.**

- Momentarily pressing the  key will reactivate the display for 30 seconds. Trend data will not be affected.
- Pressing and holding the  key will advance the paper (see pg. 7-5). Reloading the paper is allowed in this mode.
- The serial link to the PC computer will be suppressed in this mode.

## Trend Printing Mode

The Trend Printing Mode is intended for use in the output of the trend data summation to the built-in printer or to a PC for a full computer data download.

1. The Trend Printing Mode is entered after the monitor is powered down in the Data Collection Mode, and powered back up, or when the trend memory becomes full.
2. The user functions in Trend Printing Mode are:
  - The SpO<sub>2</sub> display will be blank and the heart rate display will flash **Err**. The oximetry function will be suppressed in this mode (see Fig. 4.6).
  - Pressing the % key will turn off the power. After power down, the unit will be powered up to the same Trend Printing mode.
  - Briefly pressing the  key will activate a printout (statistical sleep screening information, see Fig. 7.1) Pressing the  key during the printout will terminate the printout. Printing the printout can be repeated an unlimited number of times.
  - Pressing and holding the  key will advance the paper (see pg. 7-5). Reloading the paper is allowed in this mode.
  - Holding the  key for 6 to 8 seconds at power up will clear the trend data and switch the unit into Verification Mode (see Ch. 6).
  - The serial link to a PC will start as soon as the monitor is powered up. If a miscommunication between the monitor and the PC occurs, turning 'Off' the monitor and then back 'On' will re-establish the link. (see Appendix A for output protocol)

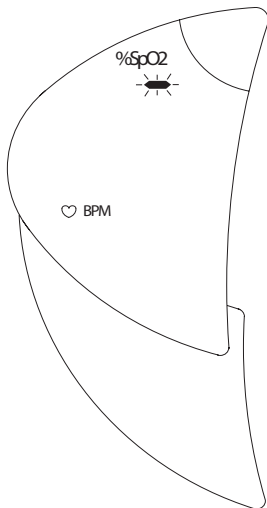


Figure 4.5: Data Collection Mode display

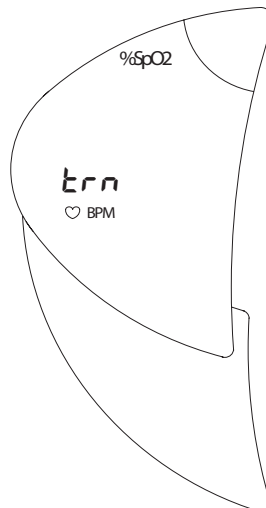


Figure 4.6: Trend Printing Mode display

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## Chapter 5: Instructions for Training the Home User

### Equipment and Supplies Checklist for Home Use

| QUANTITY | CAT. NO. | DESCRIPTION       |
|----------|----------|-------------------|
| 1        |          | Handheld Oximeter |
| 1        | 1884SSHU | Home Users Guide  |

\* The physician or home care provider will provide the type and quantity of the sensors needed for home use.

|   |      |                                                    |
|---|------|----------------------------------------------------|
| * | 3044 | Sensor, Oximetry, Adult, Finger (reusable)         |
| * | 3444 | Sensor, Oximetry, Comfort Clip® Finger             |
| 1 | 3311 | Cable, Patient (Oximetry Extension) 1.5 m (5 feet) |
| * | 1300 | Sensor, Oximetry, Disposable, Adult Finger         |
| * | 1301 | Sensor, Oximetry, Disposable, Ped. Finger          |
| * | 3049 | Adhesive Strips (Adhesive Tape)                    |

The home user may also need these supplies and reference materials:

|   |                                                                    |
|---|--------------------------------------------------------------------|
| 1 | Scissors (for trimming adhesive strips or adhesive tape).          |
| 1 | Phone number for equipment supplier in case of equipment problems. |

### Training the Home User

1. Make sure all previous trend data has been printed and that the trend memory is cleared by pressing and holding the  key for 6-8 seconds at power up.
2. Replace batteries if unsure of life expectancy (i.e. – will they last long enough to complete the sleep screening? See p.2-1 for battery life expectancy)
3. (Following the Home User's Guide while teaching these tasks may help you and the home user.) Show the home user how to:
  - visually inspect the sensor and oximetry cable.
  - connect the sensor to the oximetry cable.
  - connect the oximetry cable to the monitor.
  - turn on the monitor.
  - route the cable safely from the patient to the monitor to prevent possible entanglements and dangerous situations (tripping, strangulation) etc.
  - attach the sensor prescribed by the doctor.
  - read the SpO<sub>2</sub>, pulse rate, and pulse strength bar graph readouts displayed on the monitor.
  - know when the monitor has gone into the Data Collection Mode and how the monitors display will look.
  - turn off the monitor only upon completion of test.
  - call home care provider if monitor is accidentally turned off before test completion occurs.

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## Chapter 6: Trend Data

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### Description

Whenever the monitor is on, it stores one SpO<sub>2</sub> and one pulse rate reading every 4 seconds. The stored readings are called *trend* data. The monitor remembers trend data for at least 12 hours of run-time, possibly more, depending upon battery condition.

A summary of trend data can be printed on the built-in printer or stored data can be downloaded to a computer.

Trend data will be preserved for about one and a half minutes, without battery power, allowing battery replacement without losing trend data.

### Clearing Trend Data

1. Turn the monitor off.
2. Press and hold the  key, then turn the monitor on. Do not release the  key.
3. **CLR** will flash in the monitors' display, while the  key is pressed.
4. When **CLR** stops flashing, the trend data is cleared. Release the  key.

**NOTE! Holding the  key for 6 to 8 seconds at power up will clear the trend data and switch the unit into Verification Mode. See pg. 7-5 on use of  key for Paper Feed.**

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## Chapter 7: Printer

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### Description

Up to 12 hours of previously stored data can be printed as a summation of data from the monitors built-in printer or as a data download to a computer.

### Trend Summary Printout

To print the trend summary from the monitor's built-in printer:

1. The monitor must be in the Trend Printing Mode.
2. The Trend Printing Mode will be entered after the monitor is powered down in the Data Collection Mode or when the trend memory becomes full.
3. Press the  key to print out the summary report.
4. Press the  key again to stop printing or unit will stop printing after the summary report has been printed.

The trend summary printout from the monitor's built-in printer will contain the following sections: (see Figure 7.1: Sample Trend Printout)

1. Report Title – The first section will contain a report title to indicate that a new printout has begun.
2. Patient Information – The patient information section supplies a space for the user to write the following patient information on the printout:
  - Patient name
  - Date
  - Diagnosis
  - Comments
  - Start time
3. Study Duration – The study duration section reports the total time consumed by separating the data into the following three items:
  - Total duration
  - Excluded time (due to invalid data caused by sensor disconnect, artifact, etc.)
  - Total valid sample

4. Study Maximums and Minimums – The study maximums and minimums section contains the following information:
  - Low SpO<sub>2</sub> – The lowest recorded SpO<sub>2</sub> value taken from the total valid sample.
  - Time of Lowest SpO<sub>2</sub> – Records the time the lowest SpO<sub>2</sub> reading occurred (clock does not ignore invalid data when determining lowest SpO<sub>2</sub> time).
  - High PR – The highest recorded pulse rate value taken from the total valid sample.
  - Low PR – The lowest recorded pulse rate value taken from the total valid sample.
  - Avg. SpO<sub>2</sub> – The average SpO<sub>2</sub> value from the total valid sample.
  - SpO<sub>2</sub> STD – The standard deviation is a measure of the variability of the sample. The larger the standard deviation of the sample data, the more variability there is in the sample.<sup>1</sup>
5. Statistics – The statistics section contains information calculated from the valid data only. The following information is supplied in the statistics section:
  - % Time per SpO<sub>2</sub> range – This section displays the percent of the valid sample time that the readings were in a specified range. (Sample must be > 1% to be accounted for here.)
  - Time per SpO<sub>2</sub> range – This section displays the total valid sample time that the readings were in a specified range.
  - Total duration below 90% SpO<sub>2</sub> – This section displays the total valid sample time that the SpO<sub>2</sub> readings were below 90%.
  - Total duration 88% SpO<sub>2</sub> & below – This section displays the total valid sample time that the SpO<sub>2</sub> readings were 88% and below.
  - Longest single event with SpO<sub>2</sub> 88% & below – This section displays the duration of the longest single event when the % SpO<sub>2</sub> value was 88% or below.
  - Started at – This section displays the time the longest single event with SpO<sub>2</sub> 88% and below began.
6. Summary Complete – This final section will contain a notification that the summary is complete. This section is important because of the pauses that occur during printing.

**NOTE! Only stored data will be printed. Real-time printing is not available.**

**NOTE! The monitor uses a “relative time” clock. The times indicated on the printout are relative to the start of the study. When the monitor switches from Verification to Data Collection Mode, it restarts the “relative” time clock to 00:00:00.**

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<sup>1</sup> The standard deviation,  $s$ , is calculated by: 
$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$
 where  $x$  is the sample value,  $\bar{x}$  is the sample mean, and  $n$  is the number of samples. Note: The data sample is generally not normally distributed.

Figure 7.1: Sample Trend Printout

|                       |   |                        |                                                  |          |   |            |
|-----------------------|---|------------------------|--------------------------------------------------|----------|---|------------|
| Oximetry<br>Summary   | } | Title                  | STATISTICS                                       |          | } | Statistics |
| Patient name          |   |                        | %Time per SpO2<br>range                          |          |   |            |
| -----                 | } | Patient<br>Information | %SpO2                                            | %Time    |   |            |
| Date                  |   |                        | 95-99                                            | 19.5     |   |            |
| -----                 |   |                        | 90-94                                            | 16.1     |   |            |
| -----                 |   |                        | 85-89                                            | 16.1     |   |            |
| -----                 |   |                        | 80-84                                            | 16.1     |   |            |
| Diagnosis             |   |                        | 70-79                                            | 16.1     |   |            |
| -----                 |   |                        | 0-69                                             | 16.1     |   |            |
| -----                 | } | Study<br>Duration      | Time per SpO2<br>range                           |          |   |            |
| Comments              |   |                        | %SpO2                                            | Duration |   |            |
| -----                 |   |                        | 95-99                                            | 00:06:00 |   |            |
| -----                 |   |                        | 90-94                                            | 00:05:00 |   |            |
| Start Time            |   |                        | 85-89                                            | 00:05:00 |   |            |
| -----                 |   |                        | 80-84                                            | 00:05:00 |   |            |
| -----                 | } | Study<br>Max & Min     | 70-79                                            | 00:05:00 |   |            |
| Total duration        |   |                        | 0-69                                             | 00:05:00 |   |            |
| 00:36:00              |   |                        | Total duration<br>below 90% SpO2                 |          |   |            |
| -----                 |   |                        | 00:20:00                                         |          |   |            |
| Excluded time         |   |                        | Total duration<br>88% SpO2 &<br>below            |          |   |            |
| 00:05:00              |   |                        | 00:20:00                                         |          |   |            |
| -----                 | } | Study<br>Max & Min     | Longest single<br>event with SpO2<br>88% & below |          |   |            |
| Total valid<br>sample |   |                        | 00:31:00                                         |          |   |            |
| -----                 |   |                        | 00:20:00                                         |          |   |            |
| Low SpO2 64%          |   |                        | Started at                                       |          |   |            |
| AT 00:31:00           |   |                        | 00:15:00                                         |          |   |            |
| -----                 |   |                        | Summary                                          |          |   |            |
| High PR 105bpm        | } | End<br>Notification    | Complete                                         |          |   |            |
| Low PR 60bpm          |   |                        |                                                  |          |   |            |
| Avg SpO2 83%          |   |                        |                                                  |          |   |            |
| SpO2 STD 12%          |   |                        |                                                  |          |   |            |
| -----                 |   |                        |                                                  |          |   |            |

## What You'll Need for Printing

You'll need these items to print trend printouts:

- Oximeter with installed printer.
- Printer Paper: 1-inch wide thermal, Catalog No. 6012.

## Trend Printouts

### Collecting Trend Data

- Whenever the monitor is on, it stores one SpO<sub>2</sub> and one pulse rate reading every 4 seconds. The stored readings are called *trend* data. The monitor remembers trend data for up to 12 hours of run-time, depending upon battery life.
- Trend data will be preserved for about one and a half minutes, without battery power, allowing battery replacement without losing trend data.
- Trend memory will contain data for only one patient.
- Trends will be cleared by pressing and holding the  key for 6 to 8 seconds, at power-up. A "clr" message will flash to indicate that trend clear is about to happen.
- New data will not overwrite old data when the end of memory is reached.

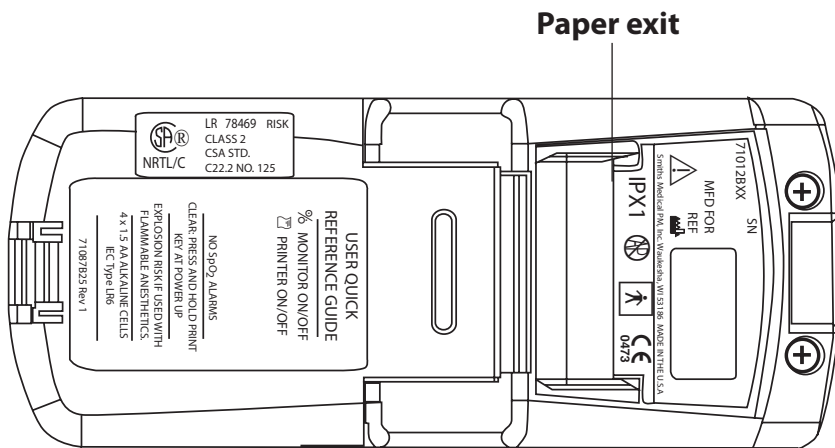
**NOTE! Turning the monitor OFF and back ON during Trend Collection will "freeze" trend information and place the monitor in the Trend Printing Mode. The monitor must have the trend data cleared and reset to begin Trend Collection again.**

## Paper Feed

To advance paper through the printer:

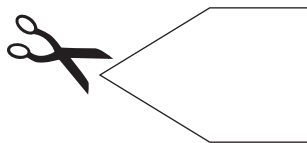
1. Press and hold  for 3 seconds (not at power up). The paper-feed will start.
2. Press the  key again to stop the printer, otherwise the printer will stop in about 25 seconds after printing 30 empty lines.
  - This is enough time to flip the device over and slide the paper end into the slot until the printer captures the paper and feeds it through.
  - If the user wants to feed the paper in a shorter period of time, the printer can be stopped by pressing the  key again.

Fig 7.2 Paper Advance



**CAUTION!** When printing, or advancing the paper, place the oximeter on it's side to prevent paper jams. Also, cutting the paper as shown below will facilitate feeding paper into the printer.

Fig 7.3 Paper Shape



**NOTE!** To tear paper off, gently pull paper towards you tightly against the cutter to tear it off. Use caution not to pull paper through the printer as this might damage the paper feed rollers.

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## Chapter 8: PC Communication Setup

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### Description

This device has been designed for use with the BCI® 1621 Oximetry Data Management Program. This device will send out trend data to a PC running the 1621 software. The 1621 software will then analyze the data and output summary information. Data are not stored in the Verification Mode. Downloading to a PC is possible only in Trend Mode. Additional materials are required to connect the device to the computer.

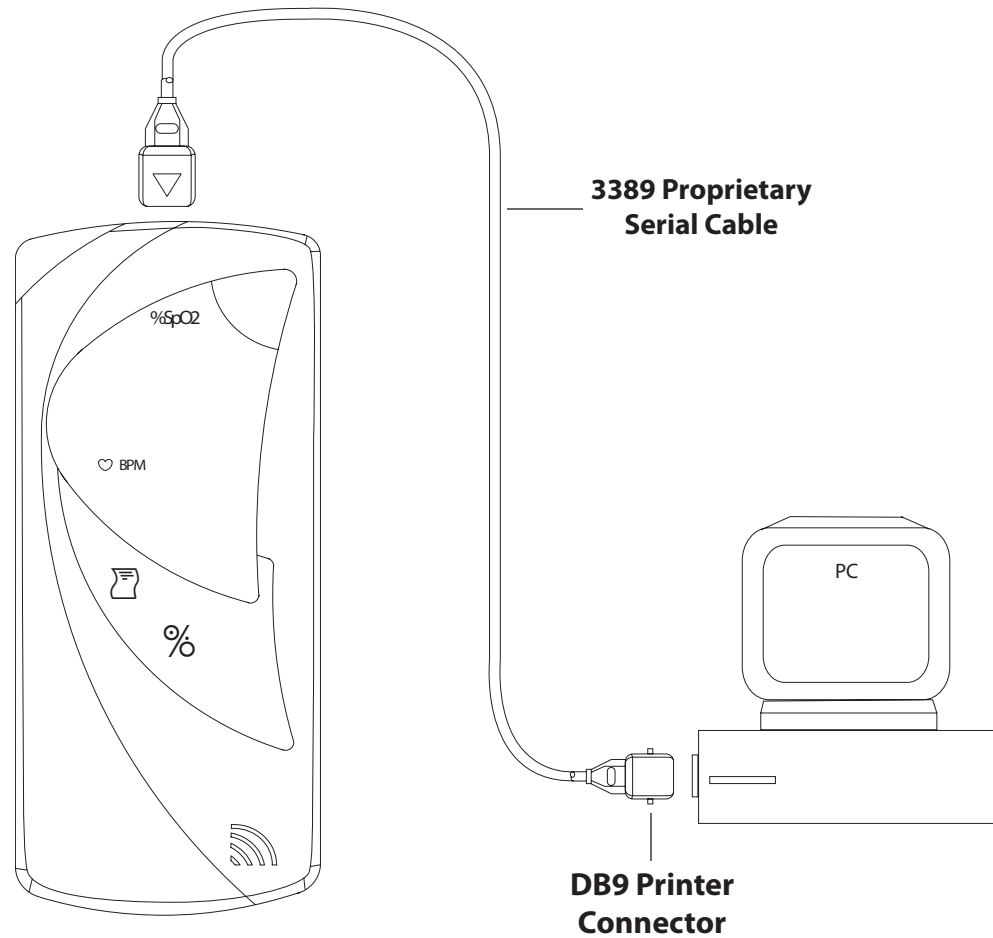
### How to Download Screenings from the Oximeter to the 1621 Software

The following items will be needed:

- 3389 Proprietary Serial Cable
  - 1621 Oximetry Data Management Program CD-ROM
1. First, the 1621 software must be installed on the PC. Please see instructions on the CD-ROM jacket for details.
  2. Set up the 1621 Oximetry software to accept the following data format :
    - Data Format: 19200 baud, 1 start bit, 8 data bits, 1 stop bit, no parity (19200 N81)
  3. After the software is installed and properly setup up, connect the female DB9 end of the 3389 serial cable to a functioning com port on the PC. Connect the male DB9 end of the 3389 cable to the pulse oximeter's sensor port.
  4. With the 1621 software running and set up to receive data, turn the oximeter on. Data transfer will begin as soon as the oximeter is turned on.

**NOTE! SEE APPENDIX A FOR DATA FORMAT INFORMATION**

Figure 8.1: PC Communication Setup



**WARNING!** The program will not function without the 3389 Proprietary Serial Cable.

**WARNING!** The program will not function if the monitor and cable are not properly connected.

**NOTE!** For more information on the downloading process, please see the operation manual in the 1621 Oximetry Data Management Program "Help" menu.

**NOTE!** See Appendix A for an alternative to the 1621 software. Appendix A contains data format information and PC communications setup instructions.

## Chapter 9: Maintenance

### Schedule of Maintenance

| MAINTENANCE                    | HOW OFTEN                                                                         | BY DOING THIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Replace battery.               | When Low Battery Indicator is flashing or 12-15 hours of battery use has elapsed. | Follow the instructions for installing the batteries.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Disinfect the reusable sensor. | Before attaching the sensor to the patient.                                       | Follow the instructions for cleaning the reusable sensor.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Disinfect the monitor.         | When necessary.                                                                   | <ol style="list-style-type: none"> <li>1. Remove the batteries from the unit.<br/><br/><i>NOTE! Print trend data before cleaning. Trend data will be lost if batteries are disconnected more than one and a half minutes.</i></li> <li>2. Wipe the surfaces of the monitor with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet.</li> </ol> <p><b>CAUTION! Do not allow isopropyl alcohol or any liquid to enter any of the openings on the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.</b></p> |

### Storage

Whenever possible, the monitor should be stored at room temperature in a dry environment.

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing.

Storage specifications are as follows:

Temperature: -40°C to +75°C (-40°F to +167°F)  
 Relative Humidity: 10% to 95% (noncondensing)

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## Chapter 10: Troubleshooting

| PROBLEM                                                                            | POSSIBLE CAUSE                                                                                                                                                                                                                            | CORRECTIVE ACTION                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No pulse shown on the bargraph.                                                    | Patient cable or sensor is disconnected from the oximeter.<br>Sensor is incorrectly positioned on the patient.<br>Poor patient perfusion.<br>Defective sensor or patient cable.<br>Monitor is in the Data Collection or Trend Print Mode. | Check sensor connections to the patient cable and to the oximeter.<br>Reposition the sensor.<br>Reposition the sensor.<br>Try a new sensor or contact your authorized repair center for help.<br>None required.                                                                                                                                         |
| Pulse rate is erratic, intermittent, or incorrect.                                 | Sensor incorrectly positioned.<br>Patient motion                                                                                                                                                                                          | Reposition the sensor.<br>Patient must remain still to obtain an accurate measurement.                                                                                                                                                                                                                                                                  |
| SpO <sub>2</sub> value is erratic, intermittent, or incorrect.                     | Poor patient perfusion.<br>Patient motion.                                                                                                                                                                                                | Reposition the sensor<br>Patient must remain still to obtain an accurate measurement.                                                                                                                                                                                                                                                                   |
| The oximeter doesn't turn on.                                                      | Batteries weak.<br>Batteries not installed or batteries incorrectly installed.                                                                                                                                                            | Replace the batteries.<br>Ensure the batteries are installed correctly.                                                                                                                                                                                                                                                                                 |
| The oximeter displays only one flashing LED with no SpO <sub>2</sub> or heart rate | The oximeter has been on continuously and collecting data for 10 minutes and has gone into the Data Collection Mode.                                                                                                                      | If not collecting trend data, press and hold the % key for 6 seconds, which will turn off the unit. To return monitor to Verification Mode, hold  key for 6 to 8 seconds at power up. This will clear the trend data and switch the unit to the Verification Mode. |
| No printout on built-in printer.                                                   | Batteries are weak.<br>Batteries are not properly installed.<br>No trends in memory.<br>Printer interface malfunction.                                                                                                                    | Replace the batteries.<br>Ensure the batteries are installed properly.<br>Take trend data.<br>Contact your authorized repair center for help.                                                                                                                                                                                                           |
| E00                                                                                | ROM Error                                                                                                                                                                                                                                 | Contact Smiths Medical PM, Inc. service representative                                                                                                                                                                                                                                                                                                  |
| E01                                                                                | RAM Error                                                                                                                                                                                                                                 | Contact Smiths Medical PM, Inc. service representative                                                                                                                                                                                                                                                                                                  |

## EMI Interference

**CAUTION!** This device has been tested and found to comply within the limits for medical devices to IEC 601-1-2:1993, EN 60601-1-2:1994, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phone, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not operate correctly.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect function. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.

If assistance is required, contact the Smiths Medical PM, Inc. Service Department or your local representative.

## Chapter 11: Optional Supplies & Accessories

| CAT. NO | DESCRIPTION                                              | QTY     |
|---------|----------------------------------------------------------|---------|
| 1300    | Sensor, Oximetry, Disposable, Adult Finger               | 10/box  |
| 1301    | Sensor, Oximetry, Disposable, Pediatric Finger, 15-45 kg | 10/box  |
| 1302    | Sensor, Oximetry, Disposable, Neonate, < 3 kg            | 10/box  |
| 1303    | Sensor, Oximetry, Disposable, Infant, 3-15 kg            | 3/box   |
| 1606    | Simulator & Cable , Oximeter, 1.5m (5 feet)              | each    |
| 1621    | Oximetry Data Management Software, CD-ROM                | each    |
| 1884SS  | Manual, Operation                                        | each    |
| 1885    | Manual, Service                                          | each    |
| 3025    | Sensor, Oximetry, Wrap, Infant, (reusable) 3-15 kg       | each    |
| 3026    | Sensor, Oximetry, Wrap, Neonate, (reusable) < 3 kg       | each    |
| 3043    | Sensor, Oximetry, Universal 'Y'                          | each    |
| 3044    | Sensor, Oximetry, Adult, Finger (reusable)               | each    |
| 3049    | Strips, Adhesive                                         | 40/pkg  |
| 3078    | Sensor, Oximetry, Ear (reusable)                         | each    |
| 3134    | Tape, Attachment, Neonatal                               | 50/pkg  |
| 3135    | Tape, Attachment, Infant                                 | 50/pkg  |
| 3136    | Tape, Attachment, Neonatal                               | 100/pkg |
| 3137    | Tape, Attachment, Infant                                 | 100/pkg |
| 3138    | Posey Wrap, Attachment, Universal 'Y'                    | 10/pkg. |
| 3178    | Sensor, Pediatric Finger, 5-45 kg                        | each    |
| 3311    | Cable, Patient (Oximetry Extension) 1.5m (5 feet)        | each    |
| 3339    | PC Adapter Cable (Alternative Connection)                | each    |
| 3350    | Cable, Printer Interface (Alternative Connection)        | each    |
| 3389    | Proprietary Serial Cable (for use with 1621 Software)    | each    |
| 3415    | Case, Carrying                                           | each    |
| 3418    | Protective Boot 3401                                     | each    |
| 3444    | Sensor, Oximetry, Comfort Clip®, Finger                  | each    |
| 6012    | Paper, Printer                                           | 4/pk    |

### Ordering Information

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. customer service department at the address or phone number below.

Smiths Medical PM, Inc.  
N7W22025 Johnson Drive  
Waukesha, Wisconsin 53186-1856

Phone: (262) 542-3100  
Fax: (262) 542-0718  
Toll-Free: (800) 558-2345 (USA only)  
Email: [info.pm@smiths-medical.com](mailto:info.pm@smiths-medical.com)

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## Chapter 12: Specifications

### Equipment Classification

|                                                  |                    |
|--------------------------------------------------|--------------------|
| Type of Protection Against Electric shock:       | Internally Powered |
| Mode of operation:                               | Continuous         |
| Degree of Protection Against ingress of Liquids: | IPX1, drip proof   |
| Degree of Mobility:                              | Portable           |
| Degree of Protection Against Electric Shock:     | Type BF            |
| Safety Requirements:                             | EN60601-1: 1990    |

### Displays, Indicators, & Keys

|                        |                                                                                                              |
|------------------------|--------------------------------------------------------------------------------------------------------------|
| SpO <sub>2</sub> :     | LED numeric display, 7.62 mm (0.30 inches) high                                                              |
| Pulse Rate:            | LED numeric display, 7.62 mm (0.30 inches) high                                                              |
| Pulse Strength:        | Logarithmically scaled 8-segment LED bargraph                                                                |
| Low Battery Indicator: | 1 Segment LED                                                                                                |
| Keys:                  | % On/Off key<br> PRINT key |

### SpO<sub>2</sub>

|                         |                                                                                                                                                                                                   |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Range:                  | 0 - 99% Functional SpO <sub>2</sub> (1% increments)                                                                                                                                               |
| Accuracy <sup>1</sup> : | ±2 at 70 - 99% less than 70% is unspecified                                                                                                                                                       |
| Alarms:                 | None                                                                                                                                                                                              |
| Averaging:              | 4 pulse beat average                                                                                                                                                                              |
| Display Response:       | The display is to functional saturation.                                                                                                                                                          |
| Display Update Rate:    | 1 Hz (SpO <sub>2</sub> ); 60 Hz (pulse strength)                                                                                                                                                  |
| Calibration:            | Factory calibrated over the range of 70% to 100% SpO <sub>2</sub> using human blood samples to functional saturation. Test methods available upon request. No in-service calibration is required. |
| Sensor:                 | Red 660nm, 2.0 mW (typical)<br>Infrared 905 nm, 2.0 - 2.4 mW (typical)                                                                                                                            |

<sup>1</sup> Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the A<sub>RMS</sub> of the value measured by the co-oximeter. The 3403 has been validated in human desaturation studies on 10 healthy adult volunteers. The study was conducted at oxygen concentrations evenly distributed over an SaO<sub>2</sub> range of 70-100%.

## Pulse Rate

|                      |                                           |
|----------------------|-------------------------------------------|
| Range:               | 30-254 BPM (1 bpm increments)             |
| Accuracy:            | $\pm 2\%$ or 2 BPM, which ever is greater |
| Averaging:           | 8 second average                          |
| Display Update Rate: | 1 Hz                                      |

## Printer

1 inch wide paper thermal printer (# 6012)  
15 characters per line with two dots between symbols  
5x7 dot characters

## Power Requirements

Four standard "AA" alkaline cells (IEC Type LR6)

## Battery Life

|                 |                                                                                                                                                                                                            |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Alkaline Cells: | 2 sleep screening cycles (1 cycle = 10 minutes with display on, 8 hours with display off, 5 minutes printing)<br>or<br>Intermittent monitoring: 1 min on, 2 min off (= 1 cycle)<br>80 hours or 1600 cycles |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Dimensions

|         |                                      |
|---------|--------------------------------------|
| Width:  | 69.85mm (2.75 inches)                |
| Height: | 167.64mm (6.6 inches)                |
| Depth:  | 36.322mm (1.43 inches)               |
| Weight: | 369 grams (13 ounces) with batteries |

## Environmental Specifications

|                    |                                                                              |
|--------------------|------------------------------------------------------------------------------|
| Operating Temp.:   | 0 to 55° C (32 to 131° F)                                                    |
| Storage Temp.:     | -40 to +75° C (-40 to +167° F)                                               |
| Relative Humidity: | 10 to 95% (storage), non-condensing<br>15 to 95% (operating), non-condensing |

---

## Appendix A: Data Format

---

### Description

The device will send out Trend Data to a PC through the sensor connector. To accomplish this, the sensor must be disconnected from the device. Additional cables are required to connect the device to a PC. The communication device will be dormant if the system is not in the Trend Printing Mode.

### Alternative PC Communication Setup (Not Using 1621 Software)

The following items will be needed:

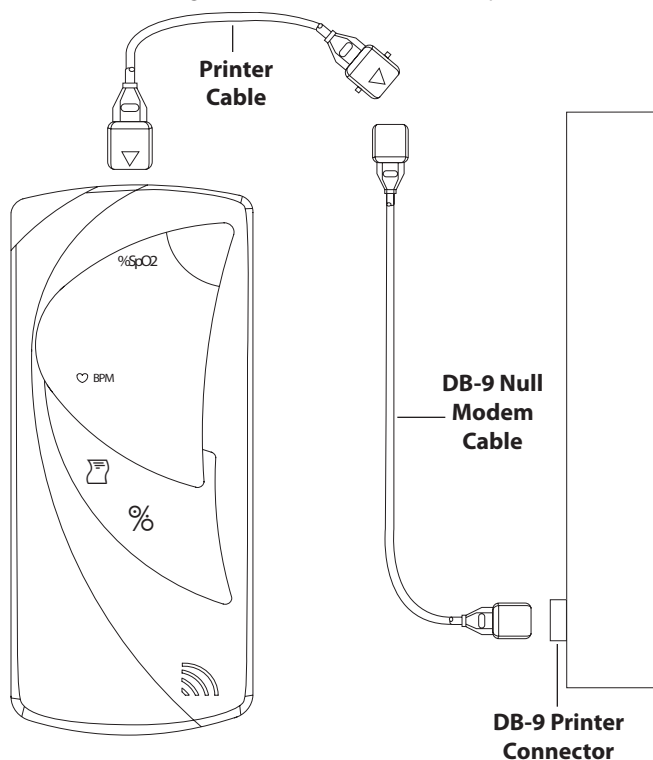
- Printer Adapter Cable (Catalog No. 3350)
- DB-9 Modem Cable (Catalog No.3339)

**NOTE! The DB9 PC Adapter Cable is an industry standard RS-232 null modem cable.**

1. Power up the monitor.
2. Connect the printer communication cable labeled “BCI” to the monitor.
3. Connect the standard RS-232 null modem cable’s DB-9 connector to the mating connector of the printer cable labeled “Printer”.
4. Connect the standard RS-232 null modem cable’s DB connector to the mating connector on the PC.

**NOTE! The DB-9 modem cable is an industry standard RS-232 null modem cable.**

Figure A.1: PC Communication Setup



## Output Data format

1. Baud rate: 19200, 8 bits, one start, one stop, no parity check.
2. Data output starts in the Trend Printing Mode as soon as power is turned on.
3. Data transmission is unidirectional from the oximeter to the receiving device. The CTS (clear-to-send) line from the receiving device to the oximeter can be used to control data flow.
4. After data pack has been sent, data communications stop, and can be resumed by cycling the power of the oximeter.

Data pack consists of binary data. The overall structure of the pack is shown in the table below:

|                    |                                                                                          |
|--------------------|------------------------------------------------------------------------------------------|
| Byte 0             | Least significant byte of the length of the data block (excluding check sum)             |
| Byte 1             | Most significant byte of the length of the data block (excluding check sum)              |
| Byte 2             | First byte of the data block                                                             |
| Byte 3             | Second byte of the data block                                                            |
| Byte 4..<br>byte n | The rest of the data block                                                               |
| Byte n+1           | Least significant byte of the check sum, which is the sum of all bytes in the data block |
| Byte n+2           | Most significant byte of the check sum                                                   |

5. As indicated in the table, each pack includes length, data block and check sum. Data in the data block represents four-second samples.
6. Data blocked is compressed. The compression method is described below.
  - Each stored data byte is split into low and high nibbles, except for the cases described later.
  - Each nibble can have a signed value in the range of -7 to 7. Bits 0 to 3 are used for SpO<sub>2</sub>, bits 4 to 7 are used for the Pulse Rate.
  - To obtain the n+1-st value, the value of the corresponding nibble should be added to the n-th value (considering sign).
 

*Note: If n-th SpO<sub>2</sub> value is 96%, and bits 0 to 3 contain a signed -1 (0xf in HEX notation), then the n+1-st value is 96% - 1 = 95%.*
  - A special case is a byte 0x88 (88-hex). This byte is used for a marker. If this marker is found in the byte sequence, the byte immediately following the marker byte is SpO<sub>2</sub> value in the range 30 to 100 (value 255 means “no data”).
  - The byte immediately following SpO<sub>2</sub> is Pulse Rate in the range of 30 to 254 (value 255 means “no data”).
  - The next byte and all sequential bytes are the bytes divided into low and high nibbles, until the next marker is found.

This method allows for almost 2:1 data compression rate.

The following table shows an example of data decompression:

| BYTE IN HEX | DECOMPRESSION                                                                                                      |
|-------------|--------------------------------------------------------------------------------------------------------------------|
| 88          | Marker byte, expect the next byte to be SpO <sub>2</sub> .                                                         |
| 60          | SpO <sub>2</sub> value, HEX 60 equals to 96% SpO <sub>2</sub> decimal, expect the next byte to be Pulse Rate       |
| 52          | Pulse Rate, HEX 52 equals to 82 bpm decimal, expect the next byte to be the byte divided into low and high nibbles |
| f0          | Low nibble is 0, SpO <sub>2</sub> = 96% + 0 = 96%;<br>High nibble is -1, Pulse Rate = 82bpm - 1 = 81 bpm           |
| ef          | Low nibble is -1, SpO <sub>2</sub> = 96% - 1 = 95%;<br>High nibble is -2, Pulse Rate = 82bpm - 2 = 80 bpm          |
| 30          | Low nibble is 0, SpO <sub>2</sub> = 95% + 0 = 95%;<br>High nibble is 3, Pulse Rate = 80bpm + 3 = 83 bpm;           |

Note! Your service representative can supply an ANSI C decompression routine.

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## Appendix B: Setting the Optional Real Time Clock

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1. Clear trend memory by pressing and holding the print key at power up until CLR stops flashing.
2. Turn the monitor off. Power on the monitor and continue to hold the on key for 6-8 seconds. The version number should be displayed and then the display will go blank except for one set of digits. This is the minutes setting.
3. Adjust the minutes by pressing the print key until the desired setting is reached.
4. Press the power key again to show the hour setting. Use the print key to set the desired hour.
5. Press the power key again to show the day setting. Use the print key to set the desired day.
6. Press the power key again to show the month setting. Use the print key to set the desired month.
7. Press the power key again to show the year setting. Use the print key to set the desired year.
8. Press the power key again to exit the time setting menu. After the power key is pressed a time stamp is printed and the monitor turns itself off.
9. Verify that the correct time stamp was printed. If the correct time and date was not printed, repeat steps 2 through 9 until the proper time and date is verified.

The time and date can be verified by repeating step 2 and then pressing the print key until the current time and date is printed and the monitor turns itself off.

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## Appendix C: Guidance and Manufacturer's Declaration

### Guidance and Manufacturer's Declaration

The 3403 pulse oximeter is intended for use in the electromagnetic environment specified in the tables within this appendix.

**NOTE! The customer or user of the 3403 pulse oximeter should ensure that it is used in such an environment.**

#### Electromagnetic Emissions - Emissions Test

| EMISSIONS TEST                                              | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT GUIDANCE                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>CISPR 11                                    | Group 1    | The 3403 pulse oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                                                                                                               |
| RF emissions<br>CISPR 11                                    | Class B    | The 3403 pulse oximeter is suitable for use in all establishments, including: <ul style="list-style-type: none"> <li>• Domestic establishments.</li> <li>• Establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</li> </ul> |
| Harmonic emissions<br>IEC 61000-3-2                         | NA         |                                                                                                                                                                                                                                                                                                            |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | NA         |                                                                                                                                                                                                                                                                                                            |

#### Electromagnetic Emissions – Immunity

| IMMUNITY                                       |                                                                                                                        | ELECTROMAGNETIC ENVIRONMENT GUIDANCE                                                                                                                                                                                        |
|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | <b>IEC 60601 TEST LEVEL</b>                                                                                            | Floors should be made of: <ul style="list-style-type: none"> <li>• Wood</li> <li>• Concrete</li> <li>• Ceramic tile</li> </ul> If floors are covered with synthetic material, the relative humidity should be at least 30%. |
|                                                | <ul style="list-style-type: none"> <li>• <math>\pm 6</math> kV contact</li> <li>• <math>\pm 8</math> kV air</li> </ul> |                                                                                                                                                                                                                             |
|                                                | <b>COMPLIANCE LEVEL</b>                                                                                                |                                                                                                                                                                                                                             |
|                                                | <ul style="list-style-type: none"> <li>• <math>\pm 6</math> kV contact</li> <li>• <math>\pm 8</math> kV air</li> </ul> |                                                                                                                                                                                                                             |

| IMMUNITY                                                                                                |                                                                                                                                                                  | ELECTROMAGNETIC ENVIRONMENT GUIDANCE                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrical fast transient/burst<br>IEC 61000-4-4                                                        | <b>IEC 60601 TEST LEVEL</b>                                                                                                                                      | A.C. Mains power voltage should be the typical quality of a: <ul style="list-style-type: none"><li>• Commercial environment.</li><li>• Hospital environment.</li></ul> |
|                                                                                                         | <ul style="list-style-type: none"><li>• NA for power supply lines.</li><li>• <math>\pm 0.25</math> kV to <math>\pm 1</math> kV for input/output lines.</li></ul> |                                                                                                                                                                        |
|                                                                                                         | <b>COMPLIANCE LEVEL</b>                                                                                                                                          |                                                                                                                                                                        |
|                                                                                                         | <ul style="list-style-type: none"><li>• NA for power supply lines.</li><li>• <math>\pm 0.25</math> kV to <math>\pm 1</math> kV for input/output lines.</li></ul> |                                                                                                                                                                        |
| Surge<br>IEC 61000-4-5                                                                                  | <b>IEC 60601 TEST LEVEL</b>                                                                                                                                      |                                                                                                                                                                        |
|                                                                                                         | NA                                                                                                                                                               |                                                                                                                                                                        |
|                                                                                                         | <b>COMPLIANCE LEVEL</b>                                                                                                                                          |                                                                                                                                                                        |
|                                                                                                         | NA                                                                                                                                                               |                                                                                                                                                                        |
| Voltage dips, short interruptions, and voltage variations on power supply input lines<br>IEC 61000-4-11 | <b>IEC 60601 TEST LEVEL</b>                                                                                                                                      |                                                                                                                                                                        |
|                                                                                                         | NA                                                                                                                                                               |                                                                                                                                                                        |
|                                                                                                         | <b>COMPLIANCE LEVEL</b>                                                                                                                                          |                                                                                                                                                                        |
|                                                                                                         | NA                                                                                                                                                               |                                                                                                                                                                        |

*Note:  $U_T$  is the A.C. mains voltage prior to application of the test level.*

| IMMUNITY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                | ELECTROMAGNETIC ENVIRONMENT GUIDANCE                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Power frequency (50/60 Hz)<br>IEC 61000-4-8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | IEC 60601 TEST LEVEL                                                                                           | Power frequency magnetic fields should be the typical levels of a: <ul style="list-style-type: none"><li>• Commercial environment</li><li>• Hospital environment</li></ul> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3 A/m                                                                                                          |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | COMPLIANCE LEVEL                                                                                               |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3 A/m                                                                                                          |                                                                                                                                                                            |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | IEC 60601 TEST LEVEL                                                                                           | Recommended separation distance:<br><br>$d = 1.2$                                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• 3 V rms</li><li>• 150 kHz to 80MHz</li></ul>                           |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | COMPLIANCE LEVEL                                                                                               |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• 3 Vrms 80% AM modulation @ 1kHz</li><li>• 150 kHz to 80 MHz.</li></ul> |                                                                                                                                                                            |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IEC 60601 TEST LEVEL                                                                                           | Recommended separation distance:<br><br>$d = 0.35 \sqrt{P}$ 80 MHz to 800 Mhz<br><br>$d = 0.70 \sqrt{P}$ 800 MHz to 2.5 GHz                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• 3 V/m</li><li>• 80 MHz to 2.5 GHz</li></ul>                            |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | COMPLIANCE LEVEL                                                                                               |                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• 10 V/m 80% AM</li><li>• 80 MHz to 2.5 GHz</li></ul>                    |                                                                                                                                                                            |
| <ul style="list-style-type: none"><li>• <math>P</math> = Manufacturer's output power in watts (W).</li><li>• <math>d</math> = Recommended distance in meters (m).</li></ul> <p>Field strengths from fixed RF transmitter watts (as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p> <p><b>CAUTION! Interference may occur in the vicinity of equipment marked with the following symbol:</b></p> <div></div> <p><i>Note: At 80 MHz and 800 MHz, the higher frequency range applies.</i></p> <p><i>Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</i></p> <p><sup>a</sup> Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 3403 pulse oximeter is used exceeds the applicable RF transmitter compliance level above, the 3403 pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 3403 pulse oximeter.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> |                                                                                                                |                                                                                                                                                                            |

## Recommended Separation Distances

The 3403 pulse oximeter is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the 3403 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3403 pulse oximeter as recommended below, according to the maximum output power of the communications equipment.

The recommended separation distances between portable and mobile RF communication equipment and the 3403 pulse oximeter is:

| RATED MAXIMUM<br>OUTPUT POWER OF RF<br>TRANSMITTER (WATTS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | SEPARATION DISTANCE ACCORDING TO THE<br>FREQUENCY OF RF TRANSMITTER (METERS) |                                          |                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------|------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 150 kHz to 80MHz<br>$d = 1.2 \sqrt{P}$                                       | 80 MHz to 800 MHz<br>$d = 0.35 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 0.7 \sqrt{P}$ |
| 0.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 0.12                                                                         | 0.035                                    | 0.07                                     |
| 0.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 0.38                                                                         | 0.11                                     | 0.22                                     |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1.2                                                                          | 0.35                                     | 0.7                                      |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3.8                                                                          | 1.1                                      | 2.2                                      |
| 100                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12                                                                           | 3.5                                      | 7.0                                      |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><i>NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</i></p> <p><i>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</i></p> |                                                                              |                                          |                                          |

**WARNING! The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.**

## Appendix D: Revision History

| REVISION | DATE    | COMMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rev. 5   | 05-2007 | <ul style="list-style-type: none"> <li>• Added new design theme frame to front cover.</li> <li>• Added the Smiths design mark to list of trademarks.</li> <li>• Updated Proprietary Note in Warranty section.</li> <li>• Updated e-mail address.</li> <li>• Changed some cautions and notes to warnings.</li> <li>• Added warning to verify that all LEDs light up upon startup of the device.</li> <li>• Added warning about the oximeter displaying dashes or erroneous values under certain conditions.</li> <li>• Added caution about certain cleaning agents.</li> <li>• Added warning about incorrectly applied sensors.</li> <li>• Updated Theory of Operation.</li> <li>• Added note about the 1606 simulator not being used to access accuracy.</li> <li>• Added note about how to tear off paper from printer.</li> <li>• Added desat study info to SpO2 Specifications section in Chapter 12.</li> <li>• Added Appendix C: Guidance and Manufacturer's Declaration.</li> <li>• Added Appendix D: Revision History.</li> <li>• Added new company logo and manufacturer's address to back cover.</li> </ul> |

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